

### **REMARKS**

As indicated above, Applicants have amended Claims 1, 14, 15, 34, 46 and 47, cancelled Claims 18-33, and added claims 57-65. Claims 1-17 and 34-65 are pending in this Application, therefore are at issue.

Of the remaining pending claims, Claims 1-3, 14-17, 34-36 and 46-47 were rejected in the parent Application under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,157,723 to Granzow et al. ("Granzow") (See May 10, 2001 Office Action). Claims 4-7, 37-40 and 48-49 were rejected in the parent Application as being unpatentable over Granzow in view of U.S. Patent No. 5,414,267 to Wakalopulos ("Wakalopulos"), and Claims 8-13, 41-45 and 50-56 were rejected as unpatentable over Granzow in view of U.S. Patent No. 5,645,796 to Caputo et al. ("Caputo") (See May 10, 2001 Office Action).

Applicants take the opportunity to address those rejections in this Preliminary Amendment.

#### **Rejections Under 35 U.S.C. §102(b)**

In the parent Application, the Examiner rejected Claims 1-3, 14-17, 34-36 and 46-47 as anticipated by Granzow. The April 10, 2001, Office Action stated that:

"Granzow et al. inherently discloses the same method and system for sterilizing and adjoining two ends of a tube exposing the ends to radiant energy for a certain period of time." [Emphasis added]

Applicants respectfully traverse this rejection, specifically with respect to the Examiner's invocation of the inherency doctrine. As previously argued in the parent Application, this is an absolutely improper rejection of the present claims. The previously submitted explanation of the "inherency doctrine" is repeated below in an attempt to clear the matter.

The Examiner rejected Claims 1-3, 14-17, 34-36 and 46-47 under 35 U.S.C. 102(b) as being anticipated by Granzow et al. However, in making this determination, the Examiner applied an inappropriate standard of law in construing the Applicants' claims. In the "Response

to Applicants' Arguments" section of the April 10, 2001 Office Action in the parent Application, Examiner stated, "The Examiner has interpreted the claims *as broad as possible* in order to find prior art that reads on the claim" (page 5, paragraph labeled 4) (emphasis added). However, the Federal Circuit has held that claims must be construed in light of the specification. In *In re Marosi*, the Federal Circuit stated, "claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation.'" 710 F.2d 799, 802; 218 U.S.P.Q. 289, 292 (Fed. Cir. 1983) (emphasis in the original).

In reading Applicants' claims in light of the specification, it is clear that the Granzow patent does not describe all elements of Applicants' claims. The Granzow patent does not allow for the movement of the conduits while they are exposed to the sterilizing energy. Instead, the Granzow patent requires that the conduits are static while exposed to the high level radiant energy. The Granzow patent states,

"To make the sterile connection, the opaque wall portions of the conduits are brought together into facing contact. The opaque wall portions are exposed to sufficient radiant energy to cause them to fuse together" (column 2, lines 1-4) (emphasis added).

Further demonstrating the inability for movement, the patent later states,

"Both bayonet 22 and slot 24 are positioned asymmetrically on the housing so that each bayonet 22 can fit into a corresponding slot 24 of an identical housing in a generally permanent, snap-fit relation...Accordingly, upon connection of a pair of housings 18, 20, they are only disconnected again with a great deal of effort" (column 3, lines 10-17) (emphasis added).

The inability to move the conduits during exposure to the radiant energy is also demonstrated in Fig. 4 which shows the two conduits in facing contact and unable to be moved while receiving radiant energy.

In stark contrast, Applicants claim the ability to move components while they are in the active sterile field. Specifically, Claim 1 has been amended to include, "moving the end of at least one of the components while exposed to the active sterile field." Claim 34 includes, "moving at least one of the prepared ends into contact with the other while in the active sterile field." Claim 46 includes, "a mechanism which moves at least one of the component ends into aligned contact with the other while maintaining the at least one open component end in the active sterile field." Since Claims 1, 34 and 46 all include the element of moving at least one component in the sterile field, and the element of movement is neither described nor taught in the Granzow patent, Applicants contend that a 102(b) rejection would be improper.

As to Claims 3 and 36, the Granzow patent makes no reference to the use of an electron beam field to produce an electron field beam two. To satisfy a 102(b) rejection the prior art must have all limitations of the Applicants' claim. Since Granzow does not describe the use of an electron beam tube, Applicants contend that a 102(b) rejection would be improper.

As to Claim 14, Granzow does not describe the insertion of an opened end of one component into the opened end of another component. In fact, Granzow only describes the connection of sealed conduits, "In accordance with this invention, a connection ... may be formed between sealed conduits" (column 1, lines 60-62) (emphasis added). Since Granzow does not describe all limitations of this claim, Applicants contend that a 102(b) rejection would be improper.

As to Claim 15, Granzow does not describe the abutting of opened ends. The Granzow patent states, "In accordance with this invention, a connection ... may be formed between sealed conduits" (column 1, lines 60-62) (emphasis added). Since Granzow does not describe all limitations of this claim, Applicants contend that a 102(b) rejection would be improper.

As to Claim 16, Granzow does not describe the step of severing at least one component end. Instead, Granzow only teaches the use of melting, "As the opaque wall portions melt, they preferably fuse together into a single sealed mass, and, due to the melting, a central aperture is formed" (column 2, lines 22-24) (emphasis added). Since Granzow does not describe all limitations of this claim, Applicants contend that a 102(b) rejection would be improper.

As to Claims 17 and 35, Granzow does not allow for the uncapping of at least one component end. Instead, Granzow only teaches the use of melting, "As the opaque wall portions melt, they preferably fuse together into a single sealed mass, and, due to the melting, a central aperture is formed" (column 2, lines 22-24) (emphasis added). Since Granzow does not describe all limitations of this claim, Applicants contend that a 102(b) rejection would be improper.

As to Claim 47, the Granzow patent does not describe the use of an electron beam instrument. Furthermore, the Granzow patent would not function as described if low voltage was used because there would not be sufficient energy to melt the opaque thermoplastic wall portions. Since Granzow does not describe the use of an electron beam instrument and in fact could not use one according to its method, Applicants contend that a 102(b) rejection would be improper.

Inherency Argument:

Regarding the Examiner's prior invocation of the inherency doctrine, the Applicants continue their request that this improper argument not be adopted by the Examiner.

The Examiner's prior rejection of the pending claims is inappropriate because: 1) the Examiner misapplied the inherency argument in view of the Granzow reference; 2) even if the argument were proper, the claimed steps do not flow from the teachings of the prior art; and 3) even if the argument were proper, the method for effecting sterilization in Granzow is not the same as the claimed invention.

First, inherency, or inherent teachings by prior art may arise in both the context of anticipation under §102, or obviousness under §103. In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995). However, it is the claiming of a new use, new function, or unknown property which is inherently present in the prior art, that the inherency concept will defeat. See In re Best, 562 F.2d 1252, 1254, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). Where the applicant claims a composition in terms of a function, property or characteristic and *the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference*, the rejection for inherency under 102 or 103 is proper. In re Best at 1255, n.4 (Emphasis added). The same rationale may also apply to product, apparatus, and process claims claimed in terms of *function, property or characteristics*. See M.P.E.P. §2112 (Emphasis added).

In the present case, a method having the step of joining ends together while exposed to the active sterile field is claimed. The claimed function, property or characteristic of this step is for sterile joining of the components. In order to be a proper inherency rejection the prior art must teach the step of joining ends within an active sterile field, but possibly to achieve a different function, property or characteristic. For instance, joining the ends within an active sterile field to provide improved rigidity in the tubing connection. The inherency argument does not allow the insertion of undisclosed elements into the prior art to form the basis of a rejection. In rejecting Claim 1-3, 14-17, 34-36 and 46-47 in view of Granzow by stating that it “inherently discloses the same method and system for sterilizing and adjoining two ends of a tube,” the Examiner has added an undisclosed element (step) as well as its function to the Granzow reference—i.e., *while exposed to the active sterile field*. Therefore, Applicants contend that a 102(b) rejection would be improper.

Second, Granzow does not disclose the step of preparing the end of each component to be joined while exposed to the active sterile field. The preparing step does not inherently flow from what is disclosed in Granzow. To support an anticipation rejection based on inherency, the

Examiner must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teachings in the prior art. The Examiner has made no such showing. Granzow does not have any reason to prepare or join the tubing ends in such a sterile field because it uses a penetrating sterilization energy. With this penetrating sterilization of the tubing ends there is no need to perform such tasks within a sterile field. Further, if there is not sufficient teaching or reason to prepare the tubing ends then such cannot logically flow from the teaching of the prior art. Thus, Granzow does not anticipate Claim 1-3, 14-17, 34-36 and 46-47.

Finally, the method of sterilization is very different than that of the present invention. Granzow uses an opaque disc of material which is melted at about 200° C by radiant energy, thereby opening a passageway. Any bacteria on the discs are killed by the heat and trapped in the rehardening of the melt (col. 4, lines 1-5). The radiant energy taught in the only example disclosed by Granzow is focused and centered on the discs (col. 3, lines 59-64). The present invention uses a sterile field which is created to form an area for manipulating the pre-sterilized tubing ends within. These methods are very different. Therefore, the Examiner's inherency rejection was inappropriate and should not be adopted.

#### **Rejections under 35 U.S.C. §103(a)**

The Examiner rejected Claims 4-7, 37-40 and 48-49 as unpatentable over Granzow in view of Wakalopulos, and Claims 8-13, 41-45 and 50-56 over Granzow in view of Caputo.

Applicants contend that 103(a) rejections would be improper.

As to Claims 4-7, 37-40 and 48-49, Wakalopulos is directed to an electron beam array for curing thin coatings. Granzow is directed to a method of forming a connection between two sealed conduits by using radiant energy to fuse the two conduits together. Specifically, the method requires a sufficiently high energy source that is able to melt the opaque wall portions in order to allow for the conduits to be joined (column 2, lines 19-24). The high temperature of the opaque wall portions is also needed to kill the bacteria (column 2, lines 25-30). The method is

dependant on the creation of a high temperature, both to sterilize and to melt the opaque wall portions to allow them to fuse. The Wakalopulos patent does not teach the use of an energy sufficient to create the high temperature required by the Granzow patent.

Unless the references suggest the particular combination themselves, they cannot show the actual invention was obvious. *In re Mahurkar Patent Litigation*, 831 F. Supp. 1354, 1374, 28 USPQ2d 1801, 1817 (N.D. Ill. 1993). Here, the references cannot even be combined. Using the low energy taught by the Wakalopulos patent for curing would render the Granzow patent inoperable. If references that do not suggest the particular combination cannot show obviousness, then surely references that cannot be functionally combined cannot show obviousness. *See Id.* The inability to functionally combine the references precludes a finding that the Granzow in view of Wakalopulos renders the Applicant's method obvious. Applicants therefore contend that a 103(a) rejection would be improper.

Regarding Claims 8-13, 41-45 and 50-56, Caputo is directed to a plasma sterilization process and apparatus using a pulsed treatment with a vaporized antimicrobial agent to kill microorganisms on an article. Granzow is directed to using sufficient radiant energy to melt opaque disks and form a sterile connection. Viewing Granzow in view of Caputo would yield two results, neither of which are claimed by the Applicant. One result is a two step process where a connection is made according to Granzow sterile connection and later resterilized using the Caputo sterilization technique. This view of Caputo yields only a superfluous later step that is not related to Applicant's invention of sterile joining. The other result is substituting Caputo's plasma technique for Granzow's use of radiant energy. This result is inoperative because the plasma technique is unable to melt the opaque disks as required by the Granzow patent.

Unless the references suggest the particular combination themselves, they cannot show the actual invention was obvious. *In re Mahurkar Patent Litigation*, 831 F. Supp. 1354, 1374, 28 USPQ2d 1801, 1817 (N.D. Ill. 1993). One cannot possibly combine Granzow and Caputo to obtain the Applicant's invention. Hence, it is not possible for these references to render

Applicant's invention obvious. Applicants therefore contend that a 103(a) rejection would be improper.

#### **Added Claims 57-65**

Applicant's have copied claims 57-65 from U.S. patent number 6,140,657 ("657") issued to Wakalopulos et al. for the purpose of an interference pursuant to 37 C.F.R. § 1.607 (MPEP § 2307). Under 35 U.S.C. 135(b), in order to be considered, claims meant to correspond to a proposed count must be added to an application within one year of the issuance date. One year from the date of issuance for the '657 patent is October 31, 2001. Therefore, these added claims should be considered timely filed. The Claims correspond as follows:

Applicants' Claim 57 is a copy of the '657 patent's Claim 1;

Applicants' Claims 58-61 are copies of the '657 patent's Claims 5-8, respectively;

Applicants' Claim 62 is a copy of the '657 patent's Claim 11;

Applicants' Claims 63-64 are copies of the '657 patent's Claims 16-17, respectively; and

Applicants' Claim 65 is a paraphrasing of the '657 patent's Claim 18.

#### **CONCLUSION**

In view of the amendments and remarks above directed to the §§ 102(b) and 103(a) rejections, Applicants submit that the present application is in condition for allowance.

Applicants respectfully request the Examiner to not enter the rejections and allow the pending claims to issue. If any informalities remain which can be corrected by Examiner's Preliminary Amendment, the examiner is requested to phone the undersigned attorney.



Baxter Docket No. DDR-5455  
W&W Docket No. 1417B P 316

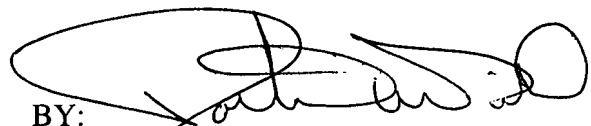
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The Commissioner is authorized to charge any fees associated with this Amendment to  
Deposit Account No. 23-0280.

Respectfully submitted,

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ATTACHMENT

Claim 1 (Amended) A method for the sterile joining of two or more pre-sterilized components comprising the steps of:

- a. sterilizing an end of each component to be joined together within an active sterile field;
- b. preparing the end of each component to be joined while exposed to the active sterile field; and
- c. moving the end of at least one of the components while exposed to the active sterile field to thereby join[ing] the prepared ends together while exposed to the active sterile field.

Claim 14 (Amended) The method of claim 2, wherein the step of moving to thereby join[ing] comprises the steps of:

- a. inserting an opened end of one component into the opened end of another component to create overlapping sections; and
- b. bonding the overlapping sections together.

Claim 15 (Amended) The method of claim 2, wherein the step of moving to thereby join[ing] comprises the steps of:

- a. abutting the opened end of one component with the opened end of another component; and
- b. welding the abutting ends together.

Claim 34 (Amended) A method for the sterile assembly of two or more pre-sterilized components together comprising the steps of:

- a. preparing at least one end of each component for assembly;
- b. sterilizing the prepared ends of each component to be assembled together within an active sterile field;
- c. [bringing] moving at least one of the prepared ends into contact with [each] the other while in the active sterile field; and
- d. assembling the prepared ends together while in the active sterile field.

Claim 46 (Amended) A system for effecting the sterile joining of at least two pre-sterilized components together comprising

- a. an active sterile field for encompassing at least one end of each component to be joined together;
- b. a surface for supporting [the] ends of the [pre-sterilized] components within the active sterile field;
- c. a mechanism which opens an end[s] of at least one of the [pre-sterilized] components while the end is supported by the surface in the active sterile field;
- d. a mechanism which [brings the opened] moves at least one of the component ends into aligned contact with [each] the other while maintaining the at least one open component end in the active sterile field; and
- e. a sealing device for bonding the [opened] aligned ends together.

Claim 47 (Amended) The system of claim 46, wherein the mechanism which [brings the opened ends into] moves at least one of the component ends into aligned contact comprises at least one mechanical actuator.